



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Roger Cady, et al.	Group No.: 1614
Serial No.: 09/575,277	Atty. Docket No.: 57294-002
Filed: 05/22/2000	
For: Preemptive Prophylaxis of Migraine	Examiner: Kim, Vickie Y.

DECLARATION UNDER 37 CFR §1.132

Roger K. Cady, having personal knowledge of facts set forth herein, hereby declares that:

1. I am an inventor of U.S. Patent Application No. 09/575,277, which was filed on May 22, 2000, for the invention entitled: Preemptive Prophylaxis of Migraine.
2. A copy of my curriculum vitae is attached hereto as Exhibit A and is incorporated by reference herein.
3. Primary headache disorders are those in which headache is the medical condition. Secondary headache disorders are those in which headache is a symptom of another pathological process.
4. Medical personnel always seek to diagnose and treat the root cause of a medical condition. In the context of migraines, medical personnel diagnose whether the migraine is a primary or secondary headache disorder. If the migraine is a primary headache disorder, the medical personnel treat the migraine. However, if the migraine is a secondary headache disorder, the medical personnel conduct further examination to identify the root cause of the headache. The present invention is directed to primary headache disorders.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signed this ^{6th}~~8th~~ day of December, 2005.

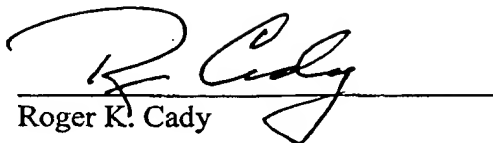

Roger K. Cady

Exhibit A

Curriculum Vitae

ROGER K. CADY, M.D.

BUSINESS ADDRESS

Headache Care Center/Clinvest
3805 S. Kansas Expressway
Springfield, MO 65804
(417) 886-2026 Fax: (417) 886-4498
rcady@primarycarenet.org

EDUCATION

Residency:

St. Francis-Mayo Family Practice Residency, LaCrosse, Wisconsin.
Chief Resident, 1980. Graduated 1980.

Medical School:

Mayo Medical School, Rochester, Minnesota.
Fall, 1973. Graduated 1977. Received Mayo Alumni Award.

Research:

Hormel Institute, January, 1973, through Fall, 1973.
Research in lipid biochemistry funded by National Institutes of Health research grant to study diolphospholipids in cell membranes.

College:

Drake University, Des Moines, Iowa, Fall, 1969 through Fall, 1972. Graduated Summa Cum Laude and Phi Beta Kappa.

PROFESSIONAL EMPLOYMENT

1997 – Present

Founder & Director, Primary Care Network, Inc., Springfield, Missouri

Director, Clinvest, Inc., Springfield, Missouri

1995 - Present

Director, Headache Care Center, Springfield, Missouri

1986 - 1995:

Medical Director, Shealy Institute, Springfield, Missouri

1984 - 1985:

Chief of Staff, St. Joseph Memorial Hospital, Hillsboro, Wisconsin

1980 - 1986:

Family Practice, Hillsboro, Wisconsin

MEDICAL LICENSE

Missouri (#R8F67)

Wisconsin (#21587)

SPECIALTY CERTIFICATION

American Board of Family Practice

PROFESSIONAL SOCIETIES

American Headache Society

American Academy of Family Physicians

American Academy of Pain Management

American College of Forensic Examiners

American Medical Association

Greene County Medical Society

International Headache Society

National Headache Foundation

CURRENT APPOINTMENTS

Abbott Laboratories Advisory Board

Allergan Advisory Board

AstaZeneca Advisory Board

Certification Examination Item Writing Committee-American Academy of Pain Management

Editorial Staff of Headache Quarterly

Elan Pharmaceuticals Advisory Board

Forest Institute of Professional Psychology, Adjunct Research Faculty

GlaxoSmithKline Advisory Board

Lester E. Cox Medical Centers, Springfield, Missouri

Merck & Company Advisory Board

Pfizer Advisory Board

CURRENT BOARD OF DIRECTORS

Clinvest, Inc.
Connect2Health, Inc.
Edus, Inc.
Headache Care Center

Holos Institute
National Headache Foundation
Primary Care Network, Inc.

BOOKS

Cady RK. Headache cluster. In M.R. Dambro (ed.), 2003 Griffith's 5 Minute Clinical Consult. Philadelphia, PA: Lippincott Williams & Wilkins, 2003, 460-461.

Kathleen Farmer, Roger K. Cady, Dennis Reeves, Joseph Bleiberg. Cognitive efficiency following migraine therapy. In: Olesen J, Steiner TJ, Lipton RB, eds. *Reducing the Burden of Headache*: Frontiers in Headache Research Series Vol. 11. New York, NY: Oxford University Press; 2003:46-51.

Curtis P. Schreiber, Roger K. Cady. Self-described 'sinus headache' and headache related impact. In: Olesen J, Steiner TJ, Lipton RB, eds. *Reducing the Burden of Headache*: Frontiers in Headache Research Series Vol. 11. New York, NY: Oxford University Press; 2003:189-193.

Cady RK, Farmer, KU, Schreiber, CP et al. Patient-Centered Strategies for Effective Management of Migraine. Springfield, MO: Primary Care Network, 2000.

Cady RK. Migraine. In M.R. Dambro (ed.), 1998 Griffith's 5 Minute Clinical Consult. Baltimore, MD: Williams & Wilkins, 1998, 678-679.

Cady RK. Cluster Headache. In M.R. Dambro (ed.), 1998 Griffith's 5 Minute Clinical Consult. Baltimore, MD: Williams & Wilkins, 1998, 448-449.

Cady RK, Farmer K. Post Traumatic Headache. In R. Windsor and D. Lox (eds.), *Soft Tissue Injuries*. Philadelphia: Hanley and Belfus, 1998, 207-224.

Cady RK, Solomon GD, Klapper J, Ryan R. Practice Standard Guidelines for Treatment of Headache. Chicago: National Headache Foundation, 1997.

Cady RK, Farmer K. Headache Free. New York: Bantam Books, 1996.

Cady RK, Klapper J, Ryan R, Mishkin B. Standards of Care for Headache Diagnosis and Treatment. Chicago: National Headache Foundation, 1996.

Cady RK. Migraine and Other Headaches. Chicago: American Medical Association, 1996.

Cady RK, Solomon GD, Tepper S, Rosum RW. Rational Therapy: Headache. Waltham, MA: Institute for Contemporary Pharmacy Research, 1995.

Cady RK, Fox AW (eds). Treating the Headache Patient. New York: Marcel Dekker, 1995.

ARTICLES

Paul L. Durham, PhD; Ryan Cady; Roger Cady, MD. Regulation of calcitonin gene-related peptide secretion from trigeminal nerve cells by botulinum toxin Type A: Implications for migraine therapy. Headache: The Journal of Head and Face Pain, 2004;44:35-43.

Frederick Taylor, MD, Susan Hutchinson, MD, Steven Graff-Radford, DDS, Roger Cady, MD, Lisa Harris, MD. Diagnosis and management of migraine. The Journal of Family Practice, (Suppl) January 2004, S1-S24.

Cady, RK, Schreiber CP, Farmer KU. Understanding the migraine Patient: The evolution from episodic headache to chronic neurological disease. Headache: The Journal of Head and Face Pain. In press

Cady, RK, Schreiber CP, Farmer KU. Understanding migraine: advancing from clinical trials to clinical practice. Headache: The Journal of Head and Face Pain. In press.

Roger K. Cady, MD; Leona D. Borchert, MD, MS; William Spalding MS; Carolyn C. Hart, BSN and Fred D. Sheftell, MD. Simple and efficient recognition of migraine with a 3-question headache screen. Headache: The Journal of Head and Face Pain. In press.

Roger K. Cady, MD; Leona D. Borchert, MD, MS; William Spalding MS; Carolyn C. Hart, BSN and Fred D. Sheftell, MD. Diagnosing migraine with a simple and efficient 3-question headache screen. Poster presentation at the 128th Annual Meeting of the American Neurological Association, San Francisco, CA, October 20, 2003

Jeff Unger, MD; Roger K. Cady, MD; Kathleen Farmer-Cady, PsyD. Part Three; Understanding migraine: strategies for prevention. Emergency Medicine, October 2003; Vol 35 No. 10, pp 39-45.

Jeff Unger, MD; Roger K. Cady, MD; Kathleen Farmer-Cady, PsyD.
Part Two; Understanding Migraine: treatment Options.
Emergency Medicine, September 2003; Vol 35 No. 9, pp 50-55.

Jeff Unger, MD; Roger K. Cady, MD; Kathleen Farmer-Cady, PsyD.
Part One; Understanding migraine: pathophysiology and presentation. Emergency
Medicine, August 2003; Vol 35 No. 8, pp 22-32.

Roger Cady, MD. Migraine in our midst: Better ways to seek and find.
CNS News: Primary Care Edition, McMahon Publishing Company,
July 2003; Vol 5. No 7.

Dowson AJ, Sender J, Lipscombe S, Cady RK, Tepper SJ, Smith R, Smith TR, Taylor
FR, Boudreau GP, Van Duijn NP, Poole AC, Baos V, Woeber C. Establishing principles
for migraine management in primary care. Int J Clin Pract 2003;57:493-507.

Roger Cady, MD; Kathleen Farmer, PsyD; Curtis Schreiber, MD. Skeletal muscle
relaxants: A new rationale for choice. Special report by Primary Care Special Edition,
McMahon Publishing Company, July 2003.

Jeff Unger, MD; Roger K. Cady, MD; Kathleen Farmer-Cady, PsyD. Migraine
Headaches, Part 3: Hormonal factors. *The Female Patient*® Vol. 28,
NO. 7 July 2003.

Jeff Unger, MD; Roger K. Cady, MD; Kathleen Farmer-Cady, PsyD. Migraine
Headaches, Part 2: Treatment options. *The Female Patient*® Vol. 28,
NO. 6 June 2003.

Jeff Unger, MD; Roger K. Cady, MD; Kathleen Farmer-Cady, PsyD. Migraine
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Eric Weidmann, MD, Jeffrey Unger, MD, Stephen Blair, MD, Christopher Friesen, DO,
Carolyn Hart, BSN, and Roger Cady, MD. An open-label study to assess changes in
efficacy and satisfaction with migraine care when patients have access to multiple
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Vol 25, Issue 1, January 2003, pgs 235-246.

Roger K. Cady, MD. Headache: Why the "default diagnosis" needs to be
migraine. *Consultant* 2002 (Suppl) Vol. 42. No. 13, S4-S5.

Roger Cady, MD; David Dodick, MD; Robert G. Kaniecki, MD; Richard B. Lipton, MD;
and Curtis Schreiber, MD. The expanding spectrum of migraine. Special Report by
Primary Care Network, published by McMahon Publishing Company, 2002.

Halpern MT, Lipton RB, Cady RK, Kwong WJ, Marlo KO, Batenhorst AS
Costs and outcomes of early versus delayed migraine treatment with sumatriptan.
Headache. 2002 Nov-Dec; 42(10):984-99.

Roger K. Cady, MD. Distinguishing “Sinus headache from migraine headache”.
John Hopkins Advanced Studies in Medicine. Vol 2, No. 16 –September 2002.

Roger K. Cady, MD. Strategies for Engaging Primary Care. Product Management
Today® Vol. 13 No. 7 July 2002

Roger K. Cady, MD, Elizabeth Loder, MD. Medical Crossfire. Improving migraine
management: the challenge before primary-care physicians Vol. 4 No. 7 July 2002.
R. Ryan, MD; G. Géraud, MD; J. Goldstein, MD; R. Cady, MD;

C. Keywood, MBBS, MRCP. Clinical Efficacy of Frovatriptan: Placebo-Controlled Studies.
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Roger K. Cady, MD, Curtis P. Schreiber, MD. Sinus headache or migraine?
Considerations in making a differential diagnosis. Neurology 58/(Suppl 6): S10-S14.

R.B. Lipton, R.K. Cady, W.F. Stewart, K. Wilks, and C. Hall. Diagnostic lessons from
the spectrum study. Neurology 58/(Suppl 6) S27-S31

Roger Cady, MD; Curtis Schreiber, MD; Kathleen Farmer, PsyD; Fred Sheftell, MD
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Roger Cady, MD, and David W. Dodick, MD. Diagnosis and treatment of migraine.
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Curtis Schreiber, MD and Roger Cady, MD. Self-described “sinus headache” and
headache related impact. In: Olesen J., Steiner, T.J., and Lipton, R.B. eds. *Reducing the
Burden of Headache* Vol. II, New York: Oxford University Press;
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M.S. Bayliss, J.B. Bjorner, M. Kosinski, C.G.H. Dahlöf, A. Dowson, R.K. Cady,
J.E. Ware Jr, and A.S. Batenhorst. Development of HIT-6™, a paper-based short form
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Roger K. Cady, Kathleen Farmer, Curtis P. Schreiber and Robert Kaniecki.
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Jennifer H. Lofland, PharmD, MPH; Susan S. Kim, PharmD; Alice S. Batenhorst, PharmD; Nelda E. Johnson, PharmD; Mary Lou Chatterton, PharmD; Roger K. Cady, MD; Robert Kaniecki, MD; and David B. Nash, MD, MBA
Cost-effectiveness and cost-benefit of sumatriptan in patients with migraine. *Mayo Clin Proc*. 2001;76:1093-1101.

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Freitag FG, Cady RK, DiSerio F, Elkind A, Gallagher RM, Goldstein J, Klapper JA, Rapoport AM, Sadowsky C, Saper JR, Smith TR. Comparative study of a combination of isometheptene mucate, dichloralphenazone with acetaminophen and sumatriptan succinate in the treatment of migraine. *Headache* 2001; 41: 391-398

Cady RK, Sheftell F, Lipton RB, Kwong WJ, O'Quin S. Economic implications of early treatment of migraine with sumatriptan tablets. *Clinical Therapeutics* 2001; 23: 284-291.

Schulman FA, Cady RK., Henry D, Batenhorst AS Putnam DG, Watson CB, O'Quinn SO. Effectiveness of sumatriptan in reducing productivity loss due to migraine: results of a randomized, double-blind, placebo-controlled clinical trial. *Mayo Clinic Proceedings* 2000; 75: 782-789.

Cady RK, Powers C., Szeto S, et al. Evaluation of migraineurs preferences for naratriptan over conventional first-line agents. *Archives of Family Medicine*. 2000; 9: 753-757.

Luciani R, Carter D, Mannix L, Hemphill M, Diamond M, Cady RK. Prevention of migraine during prodrome with naratriptan. *Cephalalgia*, 2000; 20: 122-126.

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Cady RK, Sheftell F, Lipton, RB, et al. Effect of early intervention with sumatriptan on migraine pain: retrospective analysis of data from three clinical trials. Clinical Therapeutics 2000; 22:1035-1048.

Cady RK, Lipton RB, Hall C, Stewart WF, O'Quinn S, Gutterman D. Treatment of mild headache in disabled headache sufferers: results of the spectrum study. Headache 2000; 40:792-797.

Lipton RB, Stewart WF, Cady RK, Hall C, O'Quinn S, Kuhn T, Gutterman D. Sumatriptan for the range of headaches in migraine sufferers: results of the spectrum study. Recipient of 2000 Wolff Award. Headache 2000; 40: 783-791.

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International Study Group. (Cady RK corresponding author). The long-term tolerability and efficacy of oral zolmitriptan in the acute treatment of migraine. Headache 1998;38:173-183.

Cady, RK. Computerized migraine care. Cephalalgia 1998; 18: 419-420.

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G.D. Solomon, MD; R.K. Cady, MD, J.A. Klapper, MD; N.L. Earl, MD; J.R. Saper, MD; N.M. Ramadan, MD on behalf of the 042 Clinical Trial Study Group. Clinical efficacy and tolerability of 2.5 mg zolmitriptan for the acute treatment of migraine. *Neurology* 1997;49:1219-1225.

Solomon GD, Cady RK, Klapper J, Lowy MT. For the U.S. 311C90 2.5 mg Study Group. Confirmation of the efficacy and safety of a 2.5 mg dose of 311C90 in the acute treatment of migraine. 121st Annual Meeting of the American Neurological Association, Boston, MA. April, 1997.

Cady RK. Prophylactic therapy of migraine in primary care. *Headache Quarterly* 1996; 7:6-12.

Klapper JA, Cady RK, et al. Experience with divalproex sodium as a new agent in migraine prophylaxis. *Headache Quarterly* 1996; 7: 20-23.

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Cox RH, Shealy CN, Cady RK, et al. Significant magnesium deficiency in depression. *Journal of Neurological and Orthopaedic Medicine & Surgery* 1996; 17:7-9.

Cady RK, Farmer K, Griesemer K, Sable J. Prevalence of Headache in Children. *Headache Quarterly* 1996; 7: 312-318.

Cady RK, Ryan R, Jhingran P, Pait DG, O'Quinn S. Sumatriptan injection reduces productivity loss during a migraine attack. Results of a double-blind, placebo-controlled trial. *American Academy of Neurology* (Abstract 300266). In press.

Jhingran P, Cady RK, Rubino J, Miller D, Grice RB, Gutterman DL. Improvements in health-related quality of life with sumatriptan treatment for migraine. *Journal of Family Practice* 1996; 42: 36-42.

Shealy CN, Cady RK, Cox RH, Murrell M. DHEA deficiency in Patients with chronic pain and depression. *Journal of Neurological and Orthopaedic Medicine and Surgery* 1996; 17:6.

Larry W. Halverson, MD; Roger K. Cady, MD; Merle L. Diamond, MD, FACEP and Glen D. Solomon, MD. Severe headache. Outcomes and the patient. *Hospital Physician*, April 1996;20-36.

Cady RK. Migraine and related headache disorders. *Orthopaedic Physical Therapy Clinics of North America* 1995; 4: 485-502.

Rapoport AM, Cady RK, Matthew NT, Ramadan NM, Taylor FR, Saper JR, Earl NL, Brown L. Optimizing the oral dose of 311C90 in the acute treatment of migraine. *Cephalalgia* 1995; 15(suppl 14):221.

Shealy CN, Cady RK, Cox RH. Pain, Stress and depression: psychoneurophysiology and therapy. *Stress Medicine* 1995; 11:75-77.

Halverson LW, Cady RK. Dilemmas of decision making in a case of severe headache. *Journal of Clinical Outcomes Management (JCOM)* 1995; 2

Cady RK. Migraine in women: What special considerations? *Contemporary OB/GYN* (accepted for publication).

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Cady RK. et al. Efficacy of subcutaneous sumatriptan in repeated episodes of migraine. *Journal of Neurology* June/July, 1993.

Cady RK. Advances in migraine management: focus on sumatriptan. *Resident and Staff Physician* 1993; 39: 49-56.

Cady RK and Shealy CN, Recent advances in migraine management. *The Journal of Family Practice* 1993; Vol 36, No 1; 85-91.

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Shealy CN, Cady RK. Wiener RS (ed.). Multidisciplinary pain clinics. *Innovations in Pain Management*, Paul M. Deutsch Press, Inc., Orlando, FL, 1990; 1:4-1 to 4-20.

Shealy CN, Cady RK. Wiener RS (ed.). The history of pain management. *Innovations in Pain Management*, Paul M. Deutsch Press, Inc., Orlando, FL, 1990; 1:2-1 to 2-21.

Shealy CN, Cady RK. Neurochemical response to central electrical stimulation and brain synchronization. (Abstract) VI International Rehabilitation Medicine Association; XIV National Congress of the Spanish Rehabilitation Society. *Excerpta Medica, International Congress Series* 927, June 1990, S.27.1.

Shealy CN, Cady RK, Wilkie RG, Cox RH, Liss S, Closson W. Depression: A Diagnostic, Neurochemical Profile & Therapy with Cranial Electrical Stimulation (CES). *The Journal of Neurological and Orthopaedic Medicine and Surgery*, December, 1989; 10(4):319-21.

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Shealy CN, Cady RK, Wilkie RG, Cox RH. Spinal and referred pain: nemesis of the harried physician. The Journal of Neurological and Orthopaedic Medicine and Surgery 1988; 9:305-306.

Shealy CN, Cady RK, Wilkie RG, Cox RH. Facet rhizotomy/denervation: a fifteen year experience. The Journal of Neurological & Orthopaedic Medicine & Surgery 1988; 9:107-108.

Cady RK. Electrotherapy in Medicine. California Dental Association Journal, June, 1987.

PRESENTATIONS

Dr. Cady has presented countless lectures and seminars at local, state, national, and international meetings on headache and pain disorders.

RESEARCH - Principal Investigator Abbott Laboratories

M98-845	The Safety and Efficacy of Divalproex Sodium Extended-Release Tablets in Migraine Prophylaxis: A Double-Blind, Placebo-Controlled Study.
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Allergan

191622-005	A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel Study of the Safety and Efficacy of Two Doses of BOTOX (Botulinum Toxin, Type A) Purified Neurotoxin Complex for the Prophylactic Treatment of Chronic Migraine Headaches.
191622-027-00	A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel Study to Assess the Safety and Efficacy of BOTOX (Botulinum Toxin Type A) Purified Neurotoxin Complex Injected

into Bilateral Pericranial Muscles for the Prophylactic Treatment of Chronic Tension Type Headache.

Astra Zeneca

- 311CUS/0015 A Multi-Center, Randomized, Placebo-Controlled, Double-Blind, Parallel-Group Trial to Evaluate the Efficacy and Tolerability of the Zolmitriptan 5-mg Orally Disintegrating Tablet When Taken As Soon As Possible After the Onset in the Acute Treatment of Migraine Headache.
- 311CUS/0014 A Multi-Center, Randomized, Placebo-Controlled, Double-Blind, Parallel-Group Trial to Evaluate the Efficacy and Tolerability of the Zolmitriptan (Zomig) 2.5 mg Orally Disintegrating Tablet When Taken As Soon As Possible After the Onset in the Acute Treatment of Migraine Headache.
- 311CUS/0016 A Multicenter, Randomized, Open-Label Comparison of the Effects of Zomig-ZMT (zolmitriptan) and Usual Migraine Care on Work Loss, Productivity and Patient Preference.
- 311CUS/0022 A Multi-Center, Randomized, Placebo-Controlled, Double-Blind, Parallel-Group Trial to Evaluate the Efficacy and Tolerability of the Zolmitriptan (Zomig) Nasal Spray in the Acute Treatment of Adult Subjects with Migraine.

Bayer

- 100306 A Single-Arm, Open Label Study of Cerivastatin in Community-Based Patients with Hypercholesterolemia at Risk for Cardiovascular Disease and Patients with Cardiovascular Disease.
- S98-074 A Multicenter, Prospective, Randomized, Double-Blind, Parallel Group, Single Dose, Placebo Controlled Study of the Efficacy of Extra Strength Bayer Aspirin (1000mg) in Subjects with Acute Migraine Attacks.
- 100306 "A Single-Arm, Open Label Study of Cerivastatin (Baycol®) in Community-Based Patients with Hypercholesterolemia at Risk for Cardiovascular Disease and Patients with Cardiovascular Disease.
- 100398 Prospective, Randomized, Double-Blind, Multi-Center, Comparative Trial to Evaluate the Efficacy and Safety of Ciprifloxacin Once Daily Extended Release 500 mg Tablets QD for 3 days

Bristol-Myers Squibb

- 134-01-99 Efficacy and Safety of the Combination Product Acetaminophen, Aspirin, and Caffeine Compared to Ibuprofen and to Placebo In the Acute Treatment of Migraine Attacks.
- 133-01-99 Efficacy and Safety of the Combination Product Acetaminophen, Aspirin, and Caffeine Compared to Ibuprofen and to Placebo In the Acute Treatment of Episodic Tension-Type Headaches.

Burroughs Wellcome

- 136-017 A Study to Confirm the Efficacy and Safety of 311C90 in the Treatment of Acute Migraine Headache.
- 136-15 Open Study to Investigate the Long Term Effects of Oral 311C90 in the Treatment of Migraine Headache.
- 136-042 Study to Confirm the Efficacy and Safety of a 2.5 mg. Dose of 311C90 in the Acute Treatment of Migraine Headache.

Ciba-Geigy

- 035 A Comparative Trial of Diclofenac Potassium, Ibuprofen, and Placebo in Patients with Pain Secondary to Tension-Type Headache.
- E2020-A001-211 A 20-Week Multicenter, Randomized, Double-Blind, Placebo-Controlled, Preliminary study to Evaluate the Efficacy and Safety of Two Fixed Doses (5mg and 10mg) of Donepezil Hydrochloride (E2020) in Migraine Prophylaxis.

Clinvest

The Cognitive Impact of Migraine in Children and Response to Treatment.

Oral Sumatriptan 50mg to Treat Self-Described Sinus Headache in Patients with Migraine Diagnosis.

Eisai Inc.

E2020-A001-211 A 20-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Preliminary study to Evaluate the Efficacy and Safety of two Fixed Doses (5mg and 10mg) of Donepezil Hydrochloride (E2020) in Migraine Prophylaxis.

Elan Pharmaceuticals

AN46046-228 A Double-Blind, Randomized, Multicenter, Parallel Dose Study to Evaluate the Safety and Efficacy of Zonisamide 150mg and 300mg per day and Placebo in Subjects with Migraine Headache.

Glaxo Research Institute

SUM2033 A Randomized, Double-Blind, Placebo-Controlled, In-Clinic Pilot Study to Investigate the Efficacy and Tolerability of 100mg Sumatriptan Administered as a Film-Coated, Fast Disintegrating Tablet.

SUM30045 A Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate Two Dose Levels (5mg and 20mg) of Sumatriptan Nasal Spray in the Acute Treatment of A Single Migraine Attack in Adolescent Migraineurs (12-17 years of age).

SUM40275 A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Single-Attack Evaluation of Sumatriptan 50mg and 100mg Versus Placebo During a Migraine Headache at the first Sign of Pain.

SUM40285 A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Single-Attack Evaluation of Sumatriptan 50mg and 100mg Tablets Administered During the Mild Phase of a Menstrually-Associated Migraine Attack.

SUM40286 A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Single-Attack Study of Sumatriptan 6mg Injection in the Treatment of Moderate-to-Severe Migraine Present Upon Awakening.

SUM40299 A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Tolerability of Oral Sumatriptan 25mg, 50mg and 100mg Tablets for a Single Moderate or Severe Headache in Adults Diagnosed with Migrainous Disorder (HIS 1.7).

IMT-R88	Development and Psychometric Assessment of a Patient Satisfaction Questionnaire with Migraine Therapy.
SLGA5011	A Double-Blind Randomized, Placebo-Controlled Surveillance Study of Asthma Event Outcomes in Subject Receiving Either Usual Pharmacotherapy or Usual Pharmacotherapy Plus Salmeterol 42mcg Twice Daily.
S2B-301	Evaluation of the Safety & Efficacy of Subcutaneous GR43175C in Patients with Acute Migraine Attacks.
S2B-305	Multicenter Evaluation of the Safety and Efficacy of Subcutaneous GR43175C in Patients with Acute Migraine Attacks Using A Two-Dose Regimen.
S2B-216	Safety and Efficacy of Three Doses of GR34175C in Acute Migraine Treatment.
S2B-307	Repeat-Dose Efficacy and Lab Safety Trial of Subcutaneous GR43175C in Migraine Patients.
S2B-308	Evaluation of Sumatriptan in the Treatment of Migraine Pain Recurrence - A Pilot Study.
S2B-308E	Extension of S2B-308.
S2B-211	Subcutaneous Sumatriptan as Treatment of Migraine Headache in Patients Admitted to the Emergency Department.
HOL-001	A Pilot Survey of the Cardiovascular Correlations of Migraine.
S2B-352	A to Evaluate the Safety and Efficacy of Sumatriptan Suppositories in the Acute Treatment of Three Migraine Attacks.
S2B-402	The Impact of Oral Sumatriptan on the Productivity, Quality of Life, and Health Care Use in Nursing Personnel with Migraine.
S2B-350	Imitrex Post-Marketing Surveillance Study.
S2WA3003	A Study to Evaluate the Efficacy of Oral Naratriptan in the Acute Treatment of Four Migraine Attacks.
SUMA4004	A Study to Evaluate the Impact of Imitrex Injection on Work Place Productivity Loss Due to Migraine.

S2WA3012	A Study to Evaluate the Efficacy, Safety and Tolerability of Oral Naratriptan in an Adolescent Migraine Population.
SUMA3005	A Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate Three Dose Levels of Sumatriptan Nasal Spray in the Acute Treatment of a Single Migraine Attack in Adolescent Migraineurs.
SUMA3006	An Open-Label Study to Evaluate the Long-Term Safety, Tolerability and Efficacy of Sumatriptan Nasal Spray in the Acute Treatment of Multiple Migraine Attacks in Adolescent Migraineurs.
SUMA4014	A Study to Evaluate the Efficacy of a Second Sumatriptan Succinate Tablet in the Acute Treatment of Migraine.
SUMA4013	A Randomized, Double-Blind, Double-Dummy, Crossover, Pilot Study to Compare the Efficacy and Safety of Sumatriptan 25 mg Tablets Versus Midrin Capsules in the Acute Treatment of Migraine.
SUM40294	Identification of Migraine Headache Among Self-Described and/or Physician Diagnosed Sinus Headache Sufferers and Treatment with Imitrex® 50 mg Tablets.
SUM40298	A Randomized, Double-Blind, Placebo-Controlled, Single-Attack Parallel-Group, Evaluation of the Efficacy of Sumatriptan 50mg Tablets versus Placebo in the Treatment of Self-Described and/or Physician-Diagnosed Sinus Headaches that meet International Headache Society Criteria for Migraine Headache.
IMR-01	A Randomized, Double-Blind, Placebo-Controlled Study of Oral Sumatriptan in the Acute Treatment of Disabling Primary Headaches (Migraine, Migrainous Headache, and Episodic Tension-Type Headache).
IMT-R	Evaluation of Sumatriptan Plus Celecoxib for the Acute Treatment of Migraine and for Prevention of Recurrence Following Acute Treatment of Migraine.
S2WA4006	A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Evaluation of Oral Naratriptan 1 mg and 2.5 mg Twice Daily as Prophylactic Treatment for Menstrually-Associated Migraine.
GL230018	A Study in the Prophylaxis of Migraine Headache Attacks in Adult Subjects with Migraine.

- S2W40012 A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Evaluation of Oral Naratriptan 1mg Twice Daily as Prophylactic Treatment for Menstrually-Associated Migraine.
- S2W40027 An Open-Label Evaluation of the Long-Term Safety of Oral Naratriptan 1mg Twice Daily as Prophylactic Treatment for Menstrually-Associated Migraine.
- GL230016 A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Investigate the Tolerability and Efficacy of 12-Week Oral GV196771 300mg Once Daily Compared to Placebo in the Prophylaxis of Migraine Headache.
- PRODROME Treatment of Migraine Prodrome with Naratriptan: A Pre-Emptive Approach to Migraine Care.
- ANAM/AMERGE A Pre-emptive Prophylactic Research Study Utilizing Naratriptan 2.5mg Taken When Subject Believes A Migraine Is Likely to Occur and Before the Onset of Headache Symptoms.

Janssen Pharmaceutica, Inc.

- ALN-INT-17 A Randomized, Double-Blind Placebo-Controlled Trial to Evaluate the Efficacy and Safety of Alniditan Given Subcutaneously in the Acute Treatment of Migraine.
- ALN-INT-18 Open Evaluation of the Long-Term Efficacy, Safety and Tolerability of 1.4 mg. SC Alniditan in the Acute Treatment of Migraine Attacks.

Matrix Initiatives, Inc.

MTX-002 Preliminary Assessment of Zicam Migraine Relief.

Merck & Co., Inc.

- 046-00 A Crossover Comparison of Rizatriptan and Sumatriptan.
- 049-00 A Randomized, Triple-Blind, Placebo-Controlled, Parallel-Groups, Outpatient Study to Examine the Safety, Tolerability and Efficacy of Rizatriptan (Benzoate Salt) 10 mg. RPD and 5 mg RPD for the Acute Treatment of Migraine.
- 054-00 A Randomized, Double-Blind, Placebo-Controlled, Parallel Groups, Outpatient Study to Examine the Safety, Tolerability, and Efficacy of

Rizatriptan 5 mg PO for the Acute Treatment of Migraine in Adolescents.

060-00/MAX478 A Randomized, Open-Label, Two-Period Crossover Study Comparing Preference for Rizatriptan MLT 10mg or Sumatriptan 50mg Tablet for the Acute Treatment of Migraine.

125-0 A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Outpatient Study to Examine the Safety, Tolerability, and Efficacy of Montelukast 20 mg/day P.O. and Rofecoxib 25 mg/day P.O. for the Prophylaxis of Migraine Attacks.

59-00 A Randomized, Double-Blind, Placebo-Controlled, Parallel Groups Outpatient Study to Examine the Safety, Tolerability, and Efficacy of Rizatriptan 5 mg P.O. for the Acute Treatment of Migraine in Adolescents.

MAX-US-RC-4/00 Cognitive Efficiency Following Migraine Therapy.

Mylan Pharmaceuticals, Inc.

DOT-950301 A Prospective, Randomized, Double-Blind, Placebo Controlled, Parallel Groups, Multicenter Trial Comparing Placebo and Three Doses of Dotarizine in the Prophylaxis of Migraine Headache.

Pfizer Pharmaceuticals

A1601092 An Open-Label Study of Eletriptan for the Acute Treatment of Migraine in Migraine Sufferers who are Dissatisfied with Rizatriptan Therapy.

160-102 A Study to Study of Efficacy and Safety of Oral Eletriptan in Subjects with Acute Migraine.

160-105 A Multicenter, Double-Blind, Randomized, Placebo Controlled, Parallel Group Study of the Efficacy and Safety of Oral Eletriptan in Adolescent Subjects Aged 12 to 17 years With Acute Migraine.

160-108 A Multicenter, Randomized, Open Label, Comparative Study of the Safety, Tolerantion, and Efficacy of Oral Eletriptan for Long Term Treatment of Subjects with Acute Migraine.

A1601027	Switching from Fiorinal/Fioricet to Oral Eletriptan 40 mg; Impact on Work Productivity, Quality of Life, Healthcare Use, and Subject Satisfaction in the Treatment of Acute Migraine.
P0002449	A Multicenter Study Examining the Prevalence by Severity, Frequency, and Disability of Migraine in Adult Patients in Primary Care Practices.
A1601034	An Open Label Study of Eletriptan 40mg for the Acute Treatment of Migraine in Migraine Sufferers Who Are Dissatisfied with Excedrin Migraine® Treatment.
A1601048	A Multicenter, Double-Blind, Randomized, Placebo-Controlled Parallel Group Comparative Study of the Efficacy and Safety of Oral Eletriptan (40mg) and Sumatriptan (100mg) Given for the Acute Treatment of Migraine.

Pharmacia & Upjohn

638-CNS-0059-013	Axert Clinical Experience Study (ACES)
M/3275/0011	A Long Term Open Label Safety Study of Almotriptan 12.5mg Orally in Migraine Patients.
M/3275/0008	Oral Almotriptan vs. Oral Sumatriptan in a Double-Blind Randomized, Parallel Group Study of Cost-Effectiveness and Quality of Life in Migraine.

Pozen

MT100-307	A Radomized, Double-Blind, Placebo-Controlled, Safety and Efficacy Study of MT100 in the Treatment of Migraine Prodrome.
MT300-302	A Radomized, Double-Blind, Placebo-Controlled, Evaluation of the Safety and Efficacy of MT300 in the Acute Treatment of Migraine.
MT 300	A Single Dose, Placebo-Controlled, Multicenter, Dose Ranging Trial of MT 300 in Patients with Acute Migraine Headaches.

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| MT100-301 | A Single Dose, Double-Blind, Safety and Efficacy Study of MT100, Metoclopramide Hydrochloride and Naproxen Sodium in Subjects with Acute Migraine Attacks. |
| MT100-302 | An Open-Label, Repeat Dose, Long-Term Safety Study of MT100 In Subjects with Acute Migraine Attacks. |
| MT100-201 | A Single Dose, Double-Blind, Dose Ranging, Placebo-Controlled Safety and Efficacy Study of Various Doses of Naproxen Sodium and Metoclopramide in Subjects with Acute Migraine Headaches. |

Procter & Gamble

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| 1995017 | A Study Comparing the Analgesic Effects of the Combination of Ibuprofen Plus Caffeine Relative to Ibuprofen Alone in Subjects with Acute Tension-Type Headache. |
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Purdue Frederick Research Company

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| CC90-1107 | A Comparative Study Evaluating the Safety and Analgesic Efficacy of Controlled-Release Codeine with PRN Supplements of Acetaminophen and Acetaminophen with Codeine Given as Needed in Patients with Stable Low Back Pain. |
| | A Study of the Effect of Choline Magnesium Trisalicylate on Blood Pressure Control in Hypertension Patients on a Stable Medicine Regimen. |

Sandoz Pharmaceutical Corporation

- DynaCirc Assessment Trial Analysis.
Regional Migraine Field Trial of DHE 45 Injection.
- A Study to Determine the Effectiveness and Safety of Migramist for the Acute Treatment of Migraine Headache

Vanguard Medica Ltd

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| VML/251/08 | A Double-Blind, Placebo Controlled, Parallel Group Study to Assess the Efficacy and Safety of a Single Dose of VML/251 (2.5 mg) in the Acute Treatment of Migraine. |
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VML251/96/08	A 12-Month Study of VML251 in the Acute Treatment of Migraine.
VML/251/06	A Double-Blind, Placebo Controlled, Parallel Group Study to Assess the Efficacy and Safety of a Single Dose of VML251 (2.5 mg) in the Acute Treatment of Migraine.
VML251/03	A Randomized, Double-Blind, Placebo -Controlled, Multicentre Study to Assess the Efficacy and Cardiovascular Safety of VML 251 in Patients with Known and at High Risk of Coronary Artery Disease Treating an Acute Attack of Migraine.

Vernalis

VML251/00/02	A Double-Blind, Placebo-Controlled, Three-Way Cross-Over Clinical Study to assess the Safety and Efficacy of Two Dose Regimens of Frovatriptan compared with Placebo in preventing Menstrually-Associated Migraine (MAM) headaches.
VML251/00/01	A Double-Blind, Placebo-Controlled, Two Attack Cross-Over Study to Assess the Efficacy of Frovatriptan 2.5mg Taken for Mild Headache.

Winston Laboratories

W-1001-02-01	A Double-Blind Vehicle-Controlled Evaluation of Intranasal Civamide in the Treatment of Episodic Cluster Headaches.
WL-1002-01-02	A Phase II Double-Blind Multi-Center, Vehicle-Controlled Feasibility Study of the Safety and Efficacy of Intranasal Doxepin in the Prophylactic Treatment of Chronic Daily Headache.

Zeneca

136-43	A Multicentre, Long Term Study to Maximise Migraine Relief with 311C90 (MAXIMM).
311CIL/0081	An Open, Randomized, Parallel-Group, Multicentre Trial to Compare the Efficacy of a Stratified Treatment Regimen for Acute Migraine Attacks, in which Patients Receive Therapy According to the Grade of their Migraine Disability at Baseline.
ZD6416IL/0023	A Randomized, Double-Blind, Placebo-Controlled, Crossover, Multicenter Trial to Determine the Analgesic Efficacy, Safety, and Tolerability of Treatment with Multiple Doses of ZD6416 1600mg

Administered Twice Daily in Adult Subjects with Post Herpetic Neuralgia.

311CIL/0001 A Continuation Protocol for Subjects Who Have Participated in Previous Zolmitriptan Clinical Trials.